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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2017-0235; FRL-9976-41]**

# Acetochlor; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of acetochlor in or on alfalfa and related animal commodities which are identified and discussed later in this document. Monsanto Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [*insert date of publication in the* **Federal Register**]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2017-0235, is available at *http://www.regulations.gov* or at the Office of Pesticide

Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

**FOR FURTHER INFORMATION, CONTACT:** Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0235 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0235, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

• *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

**II. Summary of Petitioned-For Tolerance**

In the **Federal Register** of February 27, 2018 (83 FR 8408) (FRL-9972-17), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 6F8533) by Monsanto Company, 1300 I Street NW, Suite 450 East, Washington DC 2005. The petition requested that 40 CFR 180.470 (a) *General*., be amended by establishing tolerances for residues of the herbicide acetochlor, (2-chloro-2'-methyl-6'-ethyl-N-ethoxymethylacetanilide), and its metabolites containing either the 2-ethyl-6-methylaniline (EMA) or the 2-(1-hydroxyethyl)-6-methyl-aniline (HEMA) moiety, to be expressed as acetochlor equivalents, resulting from applications to soil or growing crops, in or on Alfalfa, forage at 8 parts per million (ppm), Alfalfa, hay at 20 ppm, Cattle, fat at 0.02 ppm, Cattle, kidney at 0.03 ppm, Cattle, meat at 0.02 ppm, Cattle, meat byproducts, except kidney at 0.02 ppm, Goat, fat at 0.02 ppm, Goat, kidney at 0.03 ppm, Goat, meat at 0.02 ppm, Goat, meat byproducts, except kidney at 0.02 ppm, Hog, kidney at 0.02 ppm, Horse, fat at 0.02 ppm, Horse, kidney at 0.03 ppm,

Horse, meat at 0.02 ppm, Horse, meat byproducts, except kidney at 0.02 ppm, Milk at 0.02 ppm, Sheep, fat at 0.02 ppm, Sheep, kidney at 0.03 ppm, Sheep, meat at 0.02 ppm, Sheep, meat byproducts, except kidney at 0.02 ppm, and to amend 40 CFR Part 180.470 (d) *Indirect or inadvertent residues*., by adding alfalfa as an exception in the description of the commodities as follows: Animal feed, nongrass, group 18, except alfalfa, forage, and Animal feed, nongrass, group 18, except alfalfa, hay. That document referenced a summary of the petition prepared by Monsanto Company, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed 8 ppm tolerance for alfalfa forage to 8.0 ppm. The reason for this change is explained in Unit IV.D.

**III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for acetochlor including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with acetochlor follows.

*A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Acetochlor has low acute toxicity by the oral, dermal, and inhalation routes of exposure and is minimally irritating to the eyes. A dermal irritation study indicates that it is a severe skin irritant. Acetochlor is also a strong dermal sensitizer. Evidence of neurotoxicity was observed in acute and subchronic neurotoxicity screening studies in rats, developmental toxicity studies in rats, and subchronic and chronic studies in dogs. In addition to the nervous system, the major target organs affected in subchronic and chronic studies in rats, dogs, and mice exposed to acetochlor are the liver, thyroid (secondary to liver), kidney, testes, and erythrocytes. Species-specific target organs include the nasal olfactory epithelium in rats and the lungs in mice.

There is no evidence of increased qualitative or quantitative susceptibility of fetuses or offspring to acetochlor exposure in the developmental and reproduction toxicity studies in rats and rabbits. In two developmental toxicity studies in rats, fetal effects (increased early resorptions, post-implantation loss, and decreased fetal weight) occurred at doses that also

resulted in maternal toxicity (mortality, clinical signs of toxicity, and decreased maternal body weight). In two rabbit developmental toxicity studies, there were no adverse fetal effects at the highest doses tested (190 mg/kg/day and 300 mg/kg/day); whereas maternal toxicity (body weight loss) was seen at 190 mg/kg/day in one study. In three reproduction toxicity studies in rats, offspring effects (decreased pup weights in the first two studies; decreased pup weights, decreased F2 litter size at birth, and focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study) occurred at the same or higher doses than those resulting in parental toxicity (decreased body weight or weight gain in the first two studies; focal hyperplasia and polypoid adenomata in nasal epithelium of adult F1 offspring at study termination in the third study). There was no evidence of reproductive toxicity observed at any dose tested in two of the three reproductive toxicity studies in rats. The third reproduction study in rats showed a decreased number of implantations at the highest dose tested of 216 mg/kg/day.

There was evidence of carcinogenicity in studies conducted with acetochlor in rats and mice. A 23-month mouse carcinogenicity study showed weak evidence for increased benign lung tumors in females, and a 78-week study showed weak evidence for increased benign lung tumors in males. The increases were considered equivocal, based on increases in benign tumors only, inconsistent dose-responses between the two studies, inconsistencies in the responses of males and females between the two studies, lack of pre-neoplastic lung lesions in the 23-month study (while the 78-week study showed an increase in bronchiolar hyperplasia), and the variable incidence of lung tumors known to occur in older mice.

Two carcinogenicity studies in rats showed an increase in nasal epithelial tumors and thyroid follicular cell tumors. Thyroid tumor incidence was relatively low, and there was

evidence that the tumors were due to disruption of thyroid-pituitary homeostasis. There are acceptable mode of action data for the rat tumors (nasal olfactory epithelial tumors and thyroid follicular cell tumors) which are adequate to support a non-linear, margin of exposure (MOE), approach for assessment of cancer risk. The data show that, like the related compounds, alachlor and butachlor, tumor formation is dependent upon local cytotoxicity secondary to oxidative damage by a reactive quinone imine intermediate. The mechanistic data on nasal tumorigenesis of acetochlor in the rat, when considered together with the mutagenicity data on acetochlor and consistent findings in mechanistic and mutagenicity studies on the closely related compound alachlor, are considered adequate to demonstrate a cytotoxic, non-mutagenic mode of tumor induction.

Because a clear mode of action was demonstrated for the rat tumors, EPA based the cancer classification on the data from the mouse. EPA classified acetochlor as "Suggestive Evidence of Carcinogenic Potential" based on weak evidence for benign lung tumors in male and female mice and histiocytic sarcomas in female mice, and determined that linear quantification of carcinogenic potential would not be appropriate for the mouse tumors. The rat nasal tumors, with a point of departure (POD) of 10 mg/kg/day, are the most sensitive effect for cancer risk. The chronic population adjusted dose (cPAD), based on the no observed adverse effect level (NOAEL) of 2.0 mg/kg/day from the chronic dog study, will be protective of both non-cancer and cancer effects, including rat nasal tumors, thyroid tumors, and mouse tumors.

Specific information on the studies received and the nature of the adverse effects caused by acetochlor as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document *Acetochlor: Human Health Risk Assessment for*

*Proposed New Use on Alfalfa and Related Animal Commodities* at [insert page number] in docket ID number EPA-HQ-OPP-2017-0235.

*B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for acetochlor used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of January 22, 2014 (79 FR 3512) (FRL- 9904-19).

*C. Exposure Assessment*

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to acetochlor, EPA considered exposure under the petitioned-for tolerances as well as all existing acetochlor tolerances in 40 CFR 180.470. EPA assessed dietary exposures from acetochlor in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for acetochlor. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's (USDA) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed tolerance level residues except for livestock commodities where anticipated residues were used, and 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's NHANES/WWEIA. As to residue levels in food, anticipated residues from field trial data and livestock feeding studies were used, while 100% crop treated assumptions (including feed items) were made for all commodities.

iii. *Cancer*. Based on the results of carcinogenicity studies in rats and mice summarized in Unit III.A., EPA classified acetochlor as having "Suggestive Evidence of Carcinogenic Potential" but determined that the chronic risk assessment will be protective of both non-cancer and cancer effects. Therefore, a separate exposure assessment to evaluate cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetochlor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetochlor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of acetochlor for acute exposures are estimated to be 74.9 parts per billion (ppb) for surface water and 129 ppb for ground water. EDWCs for chronic exposures for non-cancer assessments are estimated to be 4.84 ppb for surface water and 82.6 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of

129.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value of 82.6 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Acetochlor is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and “other substances that have a common mechanism of toxicity.”

The chloroacetanilides have been evaluated by the Agency and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) as a related group of chemicals for this purpose. Acetochlor is included in a Cumulative Assessment Group of chloroacetanilide pesticides. For purposes of a cumulative risk assessment, it was determined that the common mechanism of toxicity group consists of alachlor, acetochlor, and butachlor. Butachlor is excluded from the group for risk assessment purposes at present because there are no registered uses or tolerances for this chemical in the U.S. The group was selected based on common endpoints of:

i. Nasal turbinate tumors in rats, and a known mechanism of toxicity for development of these tumors.

ii. Induction of hepatic uridine diphosphate-glucuronosyl transferase (UDPGT), which results in increased incidence of thyroid follicular cell tumors secondary to disruption of pituitary-thyroid homeostasis.

Thyroid effects were not included in the final cumulative assessment of the chloroacetanilide herbicides because they were determined to occur at excessively toxic dose levels, and therefore were not considered relevant to human risk assessment. Nasal tumors represent the most sensitive endpoint for both compounds.

A cumulative risk assessment of the chloroacetanilide pesticides acetochlor and alachlor was conducted in April 2007 and did not identify any cumulative risks of concern. A revised quantitative cumulative assessment was not conducted because the proposed new use on alfalfa would not affect the cumulative risk results. The new use on alfalfa is not anticipated to affect the cumulative risk results for the following reasons: the major risk driver in the cumulative assessment was alachlor in drinking water, domestic alachlor uses are being phased out (tolerances are being maintained for imported foods), cumulative dietary exposure was not of concern when accounting for the contribution from alachlor, acetochlor is a very minor contributor to chloroacetanilide cumulative risk when compared to alachlor, and acetochlor is less toxic than alachlor. No further cumulative evaluation is necessary for acetochlor use on alfalfa.

*D. Safety Factor for Infants and Children*

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. No increase in susceptibility was seen in developmental toxicity studies in rats and rabbits or in three multi-generation reproductive toxicity studies in rats. Toxicity to offspring was observed at dose levels which were the same or greater than those causing maternal or parental toxicity. Based on the results of developmental and reproductive toxicity studies, there is no concern for increased qualitative and/or quantitative susceptibility of the young following exposure to acetochlor.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for acute dietary, chronic dietary, and dermal. That decision is based on the following findings:

i. The toxicity database for acetochlor is complete for the purpose of evaluating this tolerance petition.

ii. Evidence of neurotoxicity from exposure to acetochlor was observed in several oral studies. However, these effects were typically observed at high doses. The points of departure selected for risk assessment are protective of the potential neurotoxicity observed in the database.

iii. There is no evidence that acetochlor results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction studies.

iv. There are no residual uncertainties identified in the exposure databases. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetochlor in drinking water. The acute dietary exposure analysis used tolerance level residues except for livestock commodities where anticipated residues were used and 100 PCT. The chronic dietary exposure analysis used anticipated residues from field trial data and livestock feeding studies, while 100% crop treated assumptions (including feed items) were made for all commodities and 100 PCT. These assessments will not underestimate the exposure and risks posed by acetochlor.

*E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* In examining acute aggregate risk, the only pathway of exposure relevant to the acute time frame is dietary exposure. Therefore, the acute aggregate risk is comprised of exposures to acetochlor residues in food and drinking water and is equivalent to the acute dietary risk estimates. Using the exposure assumptions discussed in this unit for acute exposure,

the acute dietary exposure from food and water to acetochlor will occupy 1.6% of the aPAD for infants < 1-year old, the population group receiving the greatest exposure.

2. *Chronic risk*. In examining chronic aggregate risk, the only pathway of exposure relevant to the chronic time frame is dietary exposure. Therefore, the chronic aggregate risk is comprised of exposures to acetochlor residues in food and drinking water and is equivalent to the chronic dietary risk. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetochlor from food and water will utilize 26% of the cPAD for all infants (< 1 year old), the population group receiving the greatest exposure. There are no residential uses for acetochlor.

3. *Short- and intermediate-term aggregate risk.* Short-term and intermediate-term aggregate exposure take into account short-term or intermediate-term residential exposure plus chronic exposure from food and water (considered to be a background exposure level). Acetochlor is not registered for any use patterns that would result in residential exposure. Therefore, the short-term or intermediate-term aggregate risk is the sum of the risk from exposure to acetochlor through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population*. The Agency has concluded that assessments using a non-linear approach (e.g. a chronic RfD-based approach) will adequately protect for all chronic toxicity, including carcinogenicity that could result from exposure to acetochlor. Chronic aggregate risk estimates are below the Agency's level of concern; therefore, cancer risk is also below the Agency's level of concern.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to acetochlor residues.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

An Enforcement Analytical Method is available to enforce the proposed tolerances. The method is a high performance liquid chromatography/oxidative coulometric electrochemical detector (HPLC/OCED) method and is listed as Method I in the Pesticide Analytical Manual (PAM) Vol. II (§ 180.470).

*B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for acetochlor on alfalfa commodities, but there are Codex MRLs established for livestock commodities at 0.02 ppm. The tolerances established

in this rulemaking are harmonized with the Codex MRLs for livestock commodities, except for the U.S. kidney tolerances, which are being established at 0.03 ppm.

*C. Revisions to Petitioned-For Tolerances*

EPA has revised the 8 ppm tolerance for alfalfa forage to 8.0 ppm, in accordance with policy. No other revisions were needed.

**V. Conclusion**

Therefore, tolerances are established for residues of acetochlor, in or on Alfalfa, forage at 8.0 ppm, Alfalfa, hay at 20 ppm, Cattle, fat at 0.02 ppm, Cattle, kidney at 0.03 ppm, Cattle, meat at 0.02 ppm, Cattle, meat byproducts, except kidney at 0.02 ppm, Goat, fat at 0.02 ppm, Goat, kidney at 0.03 ppm, Goat, meat at 0.02 ppm, Goat, meat byproducts, except kidney at 0.02 ppm, Hog, kidney at 0.02 ppm, Horse, fat at 0.02 ppm, Horse, kidney at 0.03 ppm, Horse, meat at 0.02 ppm, Horse, meat byproducts, except kidney at 0.02 ppm, Milk at 0.02 ppm, Sheep, fat at 0.02 ppm, Sheep, kidney at 0.03 ppm, Sheep, meat at 0.02 ppm, Sheep, meat byproducts, except kidney at 0.02 ppm, and to amend 40 CFR Part 180.470 (d) Indirect or inadvertent residues., by adding alfalfa as an exception in the description of the commodities as follows: Animal feed, nongrass, group 18, except alfalfa, forage, and Animal feed, nongrass, group 18, except alfalfa, hay.

**VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review

under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001); Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997); or Executive Order 13771, entitled "Reducing Regulations and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with

Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

**VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 5, 2018.

Michael Goodis,
*Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.470,

i. Add alphabetically the entries “Alfalfa, forage”; “Alfalfa, hay”; “Cattle, fat”; “Cattle, kidney”; “Cattle, meat”; “Cattle, meat byproducts, except kidney”; “Goat, fat”; “Goat, kidney”; “Goat, meat”; “Goat, meat byproducts, except kidney”; “Hog, kidney”; “Horse, fat”; “Horse, kidney”; “Horse, meat”; “Horse, meat byproducts, except kidney”; “Milk”; “Sheep, fat”; “Sheep, kidney”; “Sheep, meat“; “Sheep, meat byproducts, except kidney”; to the table in paragraph (a) and

ii. Revise the commodities “Animal feed, nongrass, group 18, except alfalfa, forage”, and “Animal feed, nongrass, group 18, except alfalfa, hay” in the table in paragraph (d).

The additions and revisions read as follows:

**§ 180.470 Acetochlor; tolerances for residues.**

(a) * * *

| Commodity | Parts per million |
|---|---|
| Alfalfa, forage | 8.0 |
| Alfalfa, hay | 20 |
| * * * * | * * * |
| Cattle, fat | 0.02 |

| | |
|---|---|
| Cattle, kidney | 0.03 |
| Cattle, meat | 0.02 |
| Cattle, meat byproducts, except kidney | 0.02 |
| * * * * | * * * |
| Goat, fat | 0.02 |
| Goat, kidney | 0.03 |
| Goat, meat | 0.02 |
| Goat, meat byproducts, except kidney | 0.02 |
| Hog, kidney | 0.02 |
| Horse, fat | 0.02 |
| Horse, kidney | 0.03 |
| Horse, meat | 0.02 |
| Horse, meat byproducts, except kidney | 0.02 |
| Milk | 0.02 |
| * * * * | * * * |
| Sheep, fat | 0.02 |
| Sheep, kidney | 0.03 |
| Sheep, meat | 0.02 |
| Sheep, meat byproducts, except kidney | 0.02 |
| * * * * | * * * |

* * * * *

(d) * * *

| Commodity | Parts per million |
| --- | --- |
| Animal feed, nongrass, group 18, except alfalfa, forage | 1.3 |
| Animal feed, nongrass, group 18, except alfalfa, hay | 3.5 |
| * * * * | * * * |

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